

### REMARKS

The Examiner rejected claims 2, 5, 11, and 23-38. Claims 11 and 23-38 have been cancelled herein without prejudice. In addition, claims 39 and 40 have been added. Claim 39 recites that the viral vector is an adenoviral vector, and claim 40 recites that the viral vector is a vaccinia virus vector. Applicants' specification fully supports these amendments. Thus, no new matter has been added.

In light of these amendments and the following remarks, Applicants respectfully request reconsideration and allowance of claims 2, 5, 39, and 40.

#### Rejections under 35 U.S.C. § 112, first paragraph

The Examiner rejected claims 23-25, 27-28, and 33-38 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement.

Applicants respectfully disagree. A person having ordinary skill in the art would have appreciated that Applicants invented the claimed subject matter. To further prosecution, however, Applicants have cancelled claims 23-25, 27-28, and 33-38 without prejudice. Thus, this rejection is moot.

The Examiner rejected claims 2, 5, 11, 23-25, 27-28, 29, 33-34, and 38 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement.

Applicants respectfully disagree. A person having ordinary skill in the art would have been able to make and use the previously claimed invention without undue experimentation. To further prosecution, however, claims 11, 23-25, 27-28, 29, 33-34, and 38 have been cancelled herein without prejudice.

Present claim 5 recites a viral vector comprising a nucleic acid encoding a therapeutic polypeptide. Claim 5 also recites that the nucleic acid is operably linked to a heterologous destabilizing element and that the heterologous destabilizing element is the 3' untranslated region of the tumor necrosis factor alpha gene. A person having ordinary skill in the art reading Applicants' specification at the time of filing would have been able to make and use such a viral vector without undue experimentation. For example, no undue experimentation is needed for a

person having ordinary skill in the art to (a) obtain a 3' untranslated region of a tumor necrosis factor alpha gene, (b) generate a viral vector containing the obtained 3' untranslated region operably linked to a nucleic acid encoding a therapeutic polypeptide, and (c) introduce the generated vector into a target cell. In fact, a person having ordinary skill in the art reading Applicants' specification at the time of filing would have had no problem making and using such a viral vector. This is particularly true given that Applicants' specification discloses multiple viral vectors that can be used to make the presently claimed invention. See, e.g., page 6, lines 18-21 of Applicants' specification. Further, Applicants' specification provides multiple working examples demonstrating the use of viral vectors containing a heterologous destabilizing element to deliver nucleic acid to different cells. See, e.g., the section extending from page 13, line 28 to page 14, line 9 and Figure 4C. Thus, taken together, it is clear that a person having ordinary skill in the art reading Applicants' specification would have been able to make and use the presently claimed viral vector without undue experimentation.

In light of the above, Applicants respectfully request withdrawal of the rejection of claims 2 and 5 under 35 U.S.C. § 112, first paragraph.

Rejections under 35 U.S.C. § 102(b)

The Examiner rejected claims 23, 30, 31, and 33-35 under 35 U.S.C. § 102(b) as allegedly being anticipated by the Risau *et al.* reference (WO 98/56936).

Applicants respectfully disagree. To further prosecution, however, claims 23, 30, 31, and 33-35 have been cancelled herein without prejudice. Thus, this rejection is moot.

Rejections under 35 U.S.C. § 103(a)

The Examiner rejected claims 2, 5, 23, 26-27, and 33-35 under 35 U.S.C. § 103(a) as allegedly being unpatentable over the Wang *et al.* reference (*Cancer Res.*, 57:5426-33 (1997)) in view of the Liu *et al.* reference (*Chinese Medical Journal*, 113:167-171 (2000)). In particular, the Examiner stated that it would have been obvious for one of ordinary skill in the art to

substitute the luciferase gene in the vector disclosed in the Wang *et al.* reference with a therapeutic gene in view of the Liu *et al.* reference.

Applicants respectfully disagree. To further prosecution, however, claims 23, 26-27, and 33-35 have been cancelled herein without prejudice. Present claim 5 recites a viral vector comprising a nucleic acid encoding a therapeutic polypeptide. Claim 5 also recites that the nucleic acid is operably linked to a heterologous destabilizing element and that the heterologous destabilizing element is the 3' untranslated region of the tumor necrosis factor alpha gene. At no point does the combination of cited references suggest that a person having ordinary skill in the art should make or use such a viral vector. For example, at no point does the combination of cited references suggest that a person having ordinary skill in the art should replace the luciferase reporter gene in the vector disclosed in the Wang *et al.* reference with any other nucleic acid, let alone a nucleic acid encoding a therapeutic polypeptide. Thus, the combination of cited references does not render the presently claimed invention obvious.

In light of the above, Applicants respectfully request withdrawal of the rejection of claims 2 and 5 under 35 U.S.C. § 103(a).

The Examiner also rejected claims 27-29 and 36-37 under 35 U.S.C. § 103(a) as allegedly being unpatentable over the Risau *et al.* reference (WO 98/56936) in view of the Sheng *et al.* reference (*J. Biol. Chem.*, 275:6628-6635 (2000)) and the Curiel *et al.* reference (*Clinical Cancer Res.*, 6:3395-3399 (2000)).

Applicants respectfully disagree. To further prosecution, however, claims 27-29 and 36-37 have been cancelled herein without prejudice. Thus, this rejection is moot.

In addition, the Examiner rejected claims 11 and 32 under 35 U.S.C. § 103(a) as allegedly being unpatentable over the Risau *et al.* reference (WO 98/56936) in view of the Montuori *et al.* reference (*FEBS Letters*, 508:379-384 (2001)) and the Curiel *et al.* reference (*Clinical Cancer Res.*, 6:3395-3399 (2000)).

Applicants respectfully disagree. To further prosecution, however, claims 11 and 32 have been cancelled herein without prejudice. Thus, this rejection is moot.

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### CONCLUSION

Applicants submit that claims 2, 5, 39, and 40 are in condition for allowance, which action is requested. The Examiner is invited to call the undersigned at the telephone number below if such will advance prosecution of this application. The Commissioner is authorized to charge any fees or credit any overpayments to Deposit Account No. 06-1050.

Respectfully submitted,

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